Docket No. (AMENDED): 14673-028C1 Application No. 10/726,960 Page 6 of 12

## REMARKS

The Office Action dated November 14, 2006 has been reviewed, and the comments of the U.S. Patent Office have been considered. Claims 1-33 are pending in this application. By this Amendment, claims 1 and 18 are amended. The amendments are supported in the specification by at least paragraph [0005] and by Figs. 2-4.

Applicant appreciates the withdrawal of the finality of the July 17, 2006 Office Action.

Claims 1-17 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-17 of co-pending Application No. 10/726,464. The rejection is respectfully traversed.

The Office Action at page 2 asserts only that instant claims 1-17 are not patentably distinct from claims 1-17 of the '464 application because:

... the longitudinal length and the interior surface area are measurements of the same area of the balloon, both remaining unchanged. When the length is unchanged it is obvious that the surface area is unchanged, and vice versa.

Assuming, arguendo, that the rejection is based on a comparison of the scope of instant claims 1-17 to the scope of claims 1-17 of the '464 application, Applicant respectfully traverses the rejection because the scope of the claims, by itself, cannot support a double patenting rejection.

See MPEP §804(II).

Applicant also traverses the rejection because the Office Action fails to establish a prima facie case of obviousness. The burden is on the Office to establish a prima facie case of obviousness as to why one of ordinary skill in the art would conclude that the inventions recited in instant claims 1-17 are an obvious variant of the invention recited in claims 1-17 of the '464 application. That is, there must be a suggestion or teaching in the '464 application that would motivate one of ordinary skill in the art to modify the invention recited in claims 1-17 of the '464 application in order to reach the invention recited in instant claims 1-17. Applicant respectfully submits that there is no suggestion or motivation provided by the Office, and the Office Action thus fails to establish a prima facie case of obviousness.

Furthermore, "length" and "area" have fundamentally different meanings and can not reasonably be viewed to be measurements of the same thing as asserted in the Office Action. The Office Action is incorrect where it asserts — without support — that "when the length is

Docket No. (AMENDED): 14673-028C1 Application No. 10/726,960 Page 7 of 12

unchanged it is obvious that the surface area is unchanged, and vice versa." The relationship between the length and the area of an object is not fixed as asserted in the Office Action. For example, in the case of a square-shaped area having a length of 2, a width of 2, and an area of 4, the length of 2 can remain unchanged and the width can be changed to 4, resulting in a change in area from 4 to 8.

Accordingly, the double patenting rejection should be withdrawn.

Claims 1-12 and 15-17 stand rejected under 35 U.S.C. §102(b) over Hamlin (U.S. Pat. No. 5,270,086); claims 18-33 stand rejected under 35 U.S.C. §102(b) over Euteneuer (U.S. Pat. No. 4,952,357); and claims 13 and 14 stand rejected under 35 U.S.C. §103(a) over Hamlin in view of Trotta (U.S. Pat. No. 5,290,306). The rejections are respectfully traversed.

With regard to independent claim 1, Hamlin fails to show or describe a non-compliant medical balloon with a first fiber layer having fibers and a second fiber layer having fibers. Hamlin does not show or describe a balloon having fibers or a fiber layer. This is because Hamlin's balloon is fabricated from a parison 40 that was extruded from a melt to form the inner layer 48 and outer layer 56 of the Hamlin balloon. See Hamlin at col. 4, lines 46-49 and 64-68. Because the polymer material used to form parison 40 was melted prior to the extrusion process, any solid structures that may have been present in the polymer material (such as fibers) were melted into a liquid. Hamlin does not describe the reconstituted polymer (post melt) that forms layers 48 or 56 to contain any fibers or to form a fiber layer. Thus, even if the pre-melt nylon material described in Hamlin at col. 2, lines 31-54, was in the form of a fiber (as asserted in the Office Action at page 6), Hamlin does not show or describe that fiber structure to be present in the post-melt layers 48 and 56 of the Hamlin balloon.

Also with regard to independent claim 1, Hamlin fails to show or describe a noncompliant medical balloon with a first fiber layer having at least one fiber disposed along a
longitudinal length of the non-compliant medical balloon. As stated above, Hamlin does not
show or describe a fiber or a fiber layer and thus could not show or describe a balloon having the
recited "at least one fiber" because Hamlin's layers 48 and 56 are formed from a melt. See
Hamlin at col. 4, lines 46-49 and 64-68. Also, Hamlin does not show or describe an arrangement
of a fiber within layers 48 and 56, or a fiber disposed along a longitudinal length of the Hamlin
balloon.

Docket No. (AMENDED): 14673-028C1 Application No. 10/726,960 Page 8 of 12

Hamlin also fails to show or describe a non-compliant medical balloon with a first fiber layer and a second fiber layer with the second fiber layer disposed over the first fiber layer such that the fibers of the first fiber layer and the fibers of the second fiber layer form an angle, as recited in claim 1. The Office Action at page 3 asserts that Fig. 5 shows fibers of layers 48 and 56 forming an angle relative to each other, but those figures do not show fibers or an angle formed between fibers. To the extent the Office Action interprets the cross hatching of Hamlin's Fig. 5 to disclose an angle, that interpretation is contrary to 37 C.F.R. §1.84(h)(3) and MPEP §608.02(IX).

Also with regard to claim 1, the Office Action improperly relies on hindsight reasoning. The Office Action at page 3 twice asserts that "with the correct combination of materials" the Hamlin balloon would possess certain features recited in claim 1. This basis for the rejection is improper hindsight reasoning because the only source for the asserted "correct combination of materials" is Applicant's own disclosure.

With regard to independent claim 18, Euteneuer fails to show or describe a noncompliant medical balloon with a first fiber and a second fiber, or a first fiber length
corresponding to a longitudinal length of the balloon. The Office Action fails to set forth a
proper rejection under 35 U.S.C. §102 because it does not explain, among other things, where
fibers are shown or described in Euteneuer. MPEP §2131 requires that each and every element
be found in the allegedly anticipating reference, but the Office Action does not explain where the
recited elements are found in Euteneuer. The only bases for the rejection of claim 18 set forth in
the Office Action are references to Euteneuer at Figs. 1 and 2B and col. 1, lines 65-68.
However, Figs. 1 and 2B do not show fibers or an arrangement of fibers relative to each other,
and col. 1, lines 65-68, regards the deposition of a film, and does not describe fibers. Euteneuer
also fails to show or describe a fiber length.

In addition to the above, the applied references fail to show or describe the features recited in dependent claims 2-17 and 19-33.

With regard to claims 2 and 24, Hamlin and Euteneuer each fail to show or describe the recited inelastic fibers because the citations relied upon in the Office Action (Hamlin at col. 2, lines 31-68, and Euteneuer at col. 2, line 49) provides no description regarding the elasticity of fibers (for Hamlin and Euteneuer) and provides only a list of pre-melt materials (for Hamlin) that could be used to form the Hamlin balloon, and none of the materials listed are described to be

Docket No. (AMENDED): 14673-028C1 Application No. 10/726,960 Page 9 of 12

inelastic fibers, and the layers 48 and 56 of the Hamlin balloon are not described to include inelastic fibers.

With regard to claims 3 and 5, Hamlin fails to show or describe the recited parallel fibers because col. 3, lines 1-8, (the citation relied upon in the Office Action) provides only a non-specific description regarding the possible combining of materials, and there is no description regarding parallel fibers.

With regard to claim 4, Hamlin fails to show describe a balloon having at least four layers that include a first fiber layer, a second fiber layer, a binding layer, and an adhesive layer. The Office Action bases the rejection of claim 4 on Hamlin at col. 2, lines 12-30, but Hamlin's "bonding inner layer" at col. 2, line 14, is the same "bonding layer" referred to at col. 2, line 55, that was <u>already cited to and relied upon</u> in the rejection of claim 1 (in regard to the recited "binding layer"). Hamlin thus fails to show or describe an adhesive layer <u>and</u> a binding layer because Hamlin describes only a single "bonding layer."

With regard to claims 6, 8, 9, 16, 20, Hamlin and Euteneuer each fail to show or describe the recited angles or arrangements because Hamlin at Figs. 4 and 5 and Euteneuer at Fig. 4 (the citations relied upon in the Office Action) do not show fibers, fiber layers, or the recited angles or arrangements.

With regard to claim 7, Hamlin fails to show or describe the recited feature and the Office Action relies on hindsight reasoning where it asserts that "with the correct combination of materials" the Hamlin balloon would possess the recited feature. The rejection is improper hindsight reasoning because the only source for the asserted "correct combination of materials" is Applicant's own disclosure.

With regard to claims 10-12, Hamlin fails to show or describe the recited coatings. The Office Action bases the rejection of these claims on Hamlin at col. 2, lines 31-68, but the materials described in that section of Hamlin are not coatings but, instead, raw materials to be used in the melt extruded by Hamlin's blow mold 42.

With regard to claims 13-14, Trotta fails to show or describe fibers and thus fails to remedy the deficiencies of Hamlin. Furthermore, the Office Action relies on Trotta for its description of a thickness of a hydrogel layer 24, which is not a thickness of a fiber or fiber layer. See Trotta at col. 4. lines 55-59.

Docket No. (AMENDED): 14673-028C1 Application No. 10/726,960 Page 10 of 12

With regard to claim 15, the Office Action fails to set forth any basis for the rejection of this claim based on Hamlin.

With regard to claim 17, Hamlin fails to show or describe a third fiber layer. The Office Action relies on Hamlin at col. 2, lines 12-30, and appears to assert that Hamlin's "bonding layer" corresponds to the recited third fiber layer. However, this interpretation of Hamlin is inconsistent because the Office Action in the rejection of claim 1 already correlates Hamlin's "bonding layer" with the recited "binding layer" and, thus, Hamlin's "bonding layer" can not also be the recited third fiber layer. Furthermore, Hamlin's "bonding layer" is not described as having fibers or otherwise being a fiber layer.

With regard to claims 19 and 25-27, Euteneuer fails to show or describe fibers or the recited materials. The Office Action bases the rejection of these claims on Euteneuer at col. 2, lines 66-67, but that citation does not describe the materials recited in these claims.

With regard to claims 21 and 22, the Office Action asserts that Euteneuer at Fig. 2 shows the recited fiber lengths. However, Euteneuer does not have a Fig. 2. Furthermore, Euteneuer's Figs. 2A-2C do not show fibers or the recited fiber lengths.

With regard to claim 23, Euteneuer fails to show or describe the recited fiber spacing. The Office Action asserts that Fig. 4 of Euteneuer shows fibers and a spacing between fibers, but that figure does not show fibers or spacing between fibers. To the extent the Office Action interprets the cross hatching of Euteneuer's Fig. 4 to disclose a fiber or a spacing between fibers, that interpretation is contrary to 37 C.F.R. §1.84(h)(3) and MPEP §608.02(IX).

With regard to claim 28, the Office Action bases the rejection on Euteneuer at col. 2, lines 48-68, but this portion of Euteneuer does not describe adhesives.

With regard to claim 29, the Office Action fails to set forth any basis for the rejection of this claim. Euteneuer fails to show or describe the recited arrangement of fibers.

With regard to claims 30-31, Euteneuer fails to show or describe a thickness of fibers.

Euteneuer's description regarding the thickness of the balloon wall does not describe the thickness of fibers, especially so because the Euteneuer balloon is not described as having fibers.

With regard to claims 32-33, the Office Action asserts that Euteneuer at col. 3, lines 34-58 describes the features of these claims. However, the cited portion of Euteneuer does not describe a wind density or length of fibers.

Docket No. (AMENDED): 14673-028C1 Application No. 10/726,960 Page 11 of 12

For the foregoing reasons, the applied references alone or in combination fail to show, describe, teach, or suggest all of the features recited in the independent claims or the dependent claims thereof. It is respectfully requested that the rejections be withdrawn.

In addition to the above, the Office Action at page 6 improperly relies on information purportedly obtained from "wikipedia.com" to support the assertion that it is common knowledge that the materials listed in Hamlin exist only in the form of fibers. This purported factual assertion is traversed by Applicant because the materials listed in Hamlin at col. 2, lines 31-54, are described as being able to take the form of a melt (see Hamlin at col. 4, lines 46-49) and thus are not exclusively limited to the form of a fiber as asserted in the Office Action. MPEP \$2144.03(C) requires the Office Action's assertion of common knowledge to be supported by documentary evidence, and any reliance on wikipedia.com can not satisfy that requirement. The wikipedia.com web site expressly states that the information contained therein is not reliable and subject to revision at any time. See http://en.wikipedia.org/wiki/Main Page (described as the "the free encyclopedia that anyone can edit."); see also http://en.wikipedia.org/wiki/Wikipedia: General disclaimer ("Wikipedia cannot guarantee the validity of the information found here. The content of any given article may recently have been changed, vandalized or altered by someone whose opinion does not correspond with the state of knowledge in the relevant fields.") Furthermore, a web site is not the "documentary evidence" required by MPEP §2144.03(C), and not contemporaneous with the filing date of the application.

Accordingly, pursuant to MPEP §2144.03(C), the Office Action's assertion of common knowledge should be withdrawn.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this Application and the prompt allowance of at least claims 1-33.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

Date: February 7, 2007 Patent Administrator Proskauer Rose LLP

Proskauer Rose LLP 1001 Pennsylvania Avenue, NW

Suite 400

Washington, DC 20004 Telephone: 202.416.6800 Facsimile: 202.416.6899 CUSTOMER NO: 61263 David W. Laub Attorney for Applicant Reg. No.: 38,708

Customer No. 61263